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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/854,786	05/14/2001	Joydeep Lahiri	SP01-129	8152

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EXAMINER
TRAN, MY CHAU T

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 02/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/854,786	Applicant(s) LAHIRI ET AL.	
	Examiner My-Chau T. Tran	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32 and 51-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32 and 51- 53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *16* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *PTO-90C* .

DETAILED ACTION

1. Applicant's amendment filed 12/2/02 in Paper No. 13 is acknowledged and entered. Claims 33-50 are canceled. Claims 1 and 51 are amended. Claims 52-53 are added. Claims 1-32 and 51-53 are pending.

Drawings

2. The color drawings (Figure 2-6) are acceptable and the petition under 37 C.F.R. 1.84(a)(2) is granted (see PTO-90C).

3. Claims 1-32 and 51-53 are treated on the merit in this Office Action.

Withdrawn Rejections

4. The previous rejections under 35 USC 112, first and second paragraph for claims 1-32 and 51 have been withdrawn in view of applicant's argument.

5. The previous rejections under 35 U.S.C. 102(b) for claims 1-6, 8-9, 11-14, 20-21, and 27-32 as being anticipated by Lang et al. (US Patent 5,756,355) have been withdrawn in view of applicant's argument that is the arrays of biological membrane microspots are not disclosed or suggested in Lang et al.

6. The previous rejections under 35 U.S.C. 103(a) for claims 7, 10, 15-19, 26 and 32 as being unpatentable over Lang et al. (US Patent 5,756,355) in view of Patton (US Patent 4,933,285) have also been withdrawn in view of applicant's argument that is the arrays of biological membrane microspots are not disclosed or suggested in Lang et al.

7. Further, the previous rejections under 35 U.S.C. 103(a) for claims 22-25 as being unpatentable over Lang et al. (US Patent 5,756,355) in view of Plant (*Langmuir*, **1999**, 15(15):5128-5135) have also been withdrawn in view of applicant's argument that is the arrays of biological membrane microspots are not disclosed or suggested in Lang et al.

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Maintained Rejections

Claim Rejections - 35 USC § 102

9. Claims 1-3, 6-9, 11-14, 20-21, and 27-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Bieri et al. (*Nature Biotechnology*, **1999**, 17(11):1105-1108).

Bieri teaches a patterned self assembled membrane bound sensor chip (Abstract; fig. 1). The sensor is comprised of a gold surface, a membrane layer that is bound to the surface through a biotinylated thiols, and G protein coupled receptors are incorporated in the membrane (pg. 1106, left col. lines 16-29; pg. 1108, left col., lines 23-40; fig. 1). The sensor chip of Bieri anticipates the claimed invention.

New Rejections – Necessitated by Amendment

Claim Rejections - 35 USC § 112

10. Claim 53 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The instant claim recites an array. The array comprises a plurality of biological membrane microspots stably associated with a surface of a glass substrate, wherein the biological membrane microspots retain their ability to bind to a ligand when stored in air.

The recitation of *'the biological membrane microspots retain their ability to bind to a ligand when stored in air'* claimed in claim 53, have no clear support in the specification and the claims as originally filed. The specification in page 3 (paragraph [0004]) disclosed 'an array comprising a plurality of biological membrane microspots associated with a surface of a substrate that can be produced, used and stored, not in an aqueous environment, but in an environment exposed to air under ambient or controlled humidities' (lines 2-5) is not support for 'the biological membrane microspots retain their ability to bind to a ligand when stored in air'.

Because the broad limitation of the specification recites that the array can be produced, used and stored, not in an aqueous environment, but in an environment exposed to air under ambient or controlled humidities, does not support the narrow limitation of the claim, which recites that the biological membrane microspots retain their ability to bind to a ligand when stored in air in the presently claimed invention. Therefore, the scope of the invention as originally disclosed in the specification would not encompassed the scope of the limitation that the biological membrane microspots retain their ability to bind to a ligand when stored in air in the presently claimed invention.

If applicants disagree, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the specification.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

12. Claims 1-3, 6-9, 11-14, and 52 are rejected under 35 U.S.C. 102(a) as being anticipated by Emili et al. (*Nature Biotechnology*, **2000**, 18(4):393-397).

Emili et al. teaches protein array (pg. 393, right col., lines 1-8; fig. 2) (referring to claim 1). One type of array disclosed by Emili et al. is comprised of a gold surface, a membrane layer that is bound to the surface through a biotinylated thiols, and G protein coupled receptors are incorporated in the membrane (pg. 395, left col. lines 32-34 to right col., lines 1-9) (referring to claim 1-3, 6-9, and 11-14). The arrays of Emili et al. anticipate the claimed invention.

Further, the limitation of "*an array that is **capable of** being produced, used, or stored in an environment exposed to air under ambient humidity*" in claim 52 should not be considered as limitations for this apparatus because these limitations represent functional language describing a use of the apparatus. See MPEP § 2114:

> Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re* Danly, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). "[A]pparatus claims cover what a device is, not what a device does." Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). (emphasis in original)
>
> A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

Therefore, "*an array that is **capable of** being produced, used, or stored in an environment exposed to air under ambient humidity*" has no patentable weight.

Claim Rejections - 35 USC § 103

13. Claims 1-9, 11-14, 20-21, 27-32, and 52-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bieri et al. (*Nature Biotechnology*, **1999**, 17(11):1105-1108) in view of Lang et al. (US Patent 5,756,355).

Bieri et al. teach a patterned self assembled membrane bound sensor chip (array) (Abstract; fig. 1). The patterned of the self-assembled membrane bound sensor chip (array) consists of alternating stripes and bars, which were produced by micro-contact printing (microspots) (pg. 1106, left col. lines 16-18). The sensor (array) is comprised of a gold surface, a membrane layer that is bound to the surface through a biotinylated thiols, and G protein coupled receptors are incorporated in the membrane (pg. 1106, left col. lines 16-29; pg. 1108, left col., lines 23-40; fig. 1). The immobilized receptor was stable both for hours and during many activation cycles (pg. 1105, right col., lines 29-30).

The array of Bieri et al. differs from the claimed invention by failing to include other type of membrane bound protein such as an ion channel associated with a surface of a substrate.

Lang et al. teach a bilayer lipid membrane sensor comprising a gold recording surface, a thiolipid layer that is anchored to the gold surface by self-assembly through an oxyethylene chain (spacer arm), an aqueous layer is trapped between the gold surface and the thiolipid layer due to the length of the spacer arm, and a second lipid layer of phospholipid (Abstract; col. 2, lines 54-67). The lipid bilayer contains a small number of biosensitive molecules (col. 1, lines 31-37).

The number (n) of oxyethylene group is from 2-10 (col. 1, lines 55-63; col. 3, lines 1-8). The lipid membrane sensor incorporates a membrane protein receptor, which can selectively bind drugs, protein, viruses, etc. from the surrounding medium, such as ion channels, G protein coupled receptors, and other receptors known in the art (col. 4, lines 57-67 to col. 5, lines 1-13).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include other type of membrane bound protein such as an ion channel associated with a surface of a substrate as taught by Lang et al. in the array of Bieri et al. One of ordinary skill in the art would have been motivated to include other type of membrane bound protein such as an ion channel associated with a surface of a substrate in the array of Bieri et al. for the advantage of providing for a sensitive assay system that can selectively bind drugs, proteins or viruses (Lang: col. 4, lines 57-59; Bieri: pg. 1105, left col., lines 23-28). Since both Bieri et al. and Lang et al. disclose a substrate incorporated membrane protein receptors (Bieri: pg. 1105, left col., lines 1-2 and 23-28; Lang: col. 4, lines 57-59).

Further, the limitation of "*an array that is **capable of** being produced, used, or stored in an environment exposed to air under ambient humidity*" in claim 52 ~~should~~ is not be considered as limitations for this apparatus because these limitations represent functional language describing a use of the apparatus. See MPEP § 2114:

> Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re* Danly, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). "[A]pparatus claims cover what a device is, not what a device does." Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). (emphasis in original)
>
> A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

Therefore, "*an array that is **capable of** being produced, used, or stored in an environment exposed to air under ambient humidity*" has no patentable weight.

The binding ability of the biological membrane of claim 53 is considered an inherent feature of the biological membrane itself because claiming of a new use, new function, or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

14. Claims 1, 7-11, 15-19, 26, 32, and 51-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bieri et al. (*Nature Biotechnology*, **1999**, 17(11):1105-1108) in view of Patton (US Patent 4,933,285).

Bieri et al. teach a patterned self assembled membrane bound sensor chip (array) (Abstract; fig. 1). The patterned of the self-assembled membrane bound sensor chip (array) consists of alternating stripes and bars, which were produced by micro-contact printing (microspots) (pg. 1106, left col. lines 16-18). The sensor (array) is comprised of a gold surface, a membrane layer that is bound to the surface through a biotinylated thiols, and G protein coupled receptors are incorporated in the membrane (pg. 1106, left col. lines 16-29; pg. 1108, left col., lines 23-40; fig. 1). The immobilized receptor was stable both for hours and during many activation cycles (pg. 1105, right col., lines 29-30).

The array of Bieri et al. differs from the claimed invention by failing to include the plastic or glass substrate and coating material such as gamma-aminopropylsilane.

Patton discloses a structure comprising monolayers of polymeric linkages used as biochemical sensors (col. 1, lines 10-17). The substrate includes inorganics such as silicon or

silicon oxide, natural and synthetic polymers, and metals such as gold (col. 3, lines 35-68 to col. 4, lines 1-6). The polymeric linkage is bifunctional with functional groups such as amino groups, or alcohols (col. 2, lines 22-38). The silicon oxide layer is covalently linked to gamma-aminopropylsilane (col. 4, lines 7-25). The polymeric linkage would provide enhanced stabilities of the immobilized biomolecules (col. 15, lines 8-20).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include the plastic or glass substrate and coating material such as gamma-aminopropylsilane as taught by of Patton in the array of Bieri et al. One of ordinary skill in the art would have been motivated to include the plastic or glass substrate and coating material such as gamma-aminopropylsilane in the array of Bieri et al. for the advantage of providing for a polymeric linkage would provide enhanced stabilities of the immobilized biomolecules and the choice of substrate such as plastic or glass would provide the advantage of economy and convenience. (Patton: col. 15, lines 8-20). Since both Bieri et al. and Patton disclose a process of immobilized structure comprising multiple monolayers of effective sequential polymeric linkages is built from the surface of a solid phase (Bieri: pg. 1108, left col., lines 23-40; Patton: col. 2, lines 54-59).

The features of remaining dependent claims are either specifically described by the reference (e.g. glass or silane compound), or constitute obvious variations in parameters which are routinely modified in the art (e.g. contact angle), and which have not been described as critical to the practice of the invention.

Further, the limitation of "*an array that is **capable of** being produced, used, or stored in an environment exposed to air under ambient humidity*" in claim 52 ~~should~~ is not be considered as

limitations for this apparatus because these limitations represent functional language describing a use of the apparatus. See MPEP § 2114:

> Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re* Danly, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). "[A]pparatus claims cover what a device is, not what a device does." Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). (emphasis in original)
>
> A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

Therefore, "*an array that is **capable of** being produced, used, or stored in an environment exposed to air under ambient humidity*" has no patentable weight.

15. Claims 1, 8-9, 20-25, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bieri et al. (*Nature Biotechnology*, **1999**, 17(11):1105-1108) in view of Plant (*Langmuir*, **1999**, 15(15):5128-5135).

Bieri et al. teach a patterned self assembled membrane bound sensor chip (array) (Abstract; fig. 1). The patterned of the self-assembled membrane bound sensor chip (array) consists of alternating stripes and bars, which were produced by micro-contact printing (microspots) (pg. 1106, left col. lines 16-18). The sensor (array) is comprised of a gold surface, a membrane layer that is bound to the surface through a biotinylated thiols, and G protein coupled receptors are incorporated in the membrane (pg. 1106, left col. lines 16-29; pg. 1108, left col., lines 23-40; fig. 1). The immobilized receptor was stable both for hours and during many activation cycles (pg. 1105, right col., lines 29-30).

The array of Bieri et al. differs from the claimed invention by failing to include the thioalkyl compound.

Plant disclosed hybrid bilayers containing thiol-derivatized alkane moieties plus natural lipids providing a biomimetric matrix that permits the successful reconstruction of membrane protein activity (Abstract). The alkanethiol is a self assembled monolayer (pg. 5128, right col., lines 11-21; fig.1). The alkanethiols would provide the distinct advantage of a complete hydrophobic layer at the metal surface and the driving force for the formation of complete bilayers (pg. 5128, right col., lines 28-38 to pg. 5129, left col., lines 18-37).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include the thioalkyl compound as taught by of Plant in the array of Bieri et al. One of ordinary skill in the art would have been motivated to include the thioalkyl compound in the array of Bieri et al. for the advantage of providing for a complete hydrophobic layer at the metal surface and the driving force for the formation of complete bilayers. Since both Bieri et al. and Plant disclose a substrate incorporated membrane protein receptors (Bieri: pg. 1105, left col., lines 1-2 and 23-28; Plant: pg. 5132, right col., lines 30-63).

Further, the limitation of "*an array that is **capable of** being produced, used, or stored in an environment exposed to air under ambient humidity*" in claim 52 ~~should~~ is not be considered as limitations for this apparatus because these limitations represent functional language describing a use of the apparatus. See MPEP § 2114:

> Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re* Danly, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). "[A]pparatus claims cover what a device is, not what a device does." Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). (emphasis in original)
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> A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

Therefore, "*an array that is **capable of** being produced, used, or stored in an environment exposed to air under ambient humidity*" has no patentable weight.

Response to Arguments

16. Applicant's arguments in view of the rejection under 35 U.S.C. 102(b) of Claims 1-3, 6-9, 11-14, 20-21, and 27-32 as being anticipated by Bieri et al. (*Nature Biotechnology*, **1999**, 17(11):1105-1108) filed on 12/2/02 have been fully considered but they are not persuasive.

Applicant contends that Bieri et al. disclose an array comprised of stripes of membranes on a substrate, not microspots. In addition, Bieri et al. fails to teach or suggest arrays that capable of being produced, stored or used in an environment exposed to air under ambient humidity.

It is the examiner position that the "comprises" terminology of the instant Claim 1 is open-ended and does not exclude the shape of the array such as those described by Bieri et al. Further, the "microspots" on the array as define in the specification on pg. 8 (paragraph [0031], lines 7-10) "*may be any convenient shape, but will typically be circular, elliptoid, oval, annular, or some other analogously curved shape, **where the shape may**, in certain embodiments, **be a result of the particular method employed to produced the array**"* and on pg. 15 (paragraph [0053], lines 1-2; [0054], lines 1-3) "*the arrays of the present invention are prepared using micropatterning techniques.... the printing process may involve ring shaped pins, **square pins**, or point pins, etc."* The array of Bieri et al. are *"patterned SAMs consisting of alternating stripes and bars of a mixed SAM were **produced by micro-contact printing**"* (pg. 1106, left col.

lines 16-18). Therefore, the array of Bieri et al. would anticipate the "microspots" on the array of the presently claimed invention.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the membrane remains adsorbed when drawn through an air-water interface) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

17. Applicant's amendment and submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 12/2/02 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a) and MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner is on ***Increased Flex Schedule*** and can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

mct
February 15, 2003

PADMASHRI PONNALURI
PRIMARY EXAMINER